

AxiChrom™ columns

CHROMATOGRAPHY COLUMNS

The AxiChrom™ column platform (Fig 1) is an innovative concept in column chromatography, which simplifies column handling from pilot to large-scale production. The novel design of AxiChrom columns makes process chromatography easier, safer, and more efficient than with conventional chromatography columns.

The AxiChrom column line has been designed and verified for exceptional performance with a broad range of resins. This includes traditional BioProcess™ resins, such as the Sepharose™ family, as well as high-flow resins such as Capto™ and MabSelect™. Excellent compatibility of chromatography columns, resins, and systems enable reliable results and high productivity.

AxiChrom columns are:

- Intelligent: reduced operation time through automation, verified methods, and simplified workflows.
- Intuitive: increased uptime through simple design with reduced risk for operator errors.
- Predictable: quick and easy technology-transfer through scalable and robust platform design.

Column description

General

AxiChrom columns are low-pressure, axial compression chromatography columns for use during process development and manufacturing of biopharmaceutical products. AxiChrom is a configurable, yet standardized platform, which enables many configuration possibilities to fit different needs. This attribute, in combination with automated packing and easy maintenance, make the platform an excellent choice for multipurpose facilities. The platform is also a great solution for manufacturing networks in need of a robust and standardized column solution.

A range of column sizes is available, from 50 to 2000 mm inner diameter (i.d.). All have a thoughtful design for easy handling and maintenance. The smaller columns, 50 to 200 mm i.d., have a stand with a pivot design. In larger columns, 300 to 2000 mm i.d., the tube swings out allowing hoist-free handling. The swing-out function is an example of how the design enables a significant reduction in handling time, compared to other column series.



Fig 1. A selection of columns from the AxiChrom platform.

Handling AxiChrom columns is easy using Intelligent Packing, which enables creation of automated methods for packing, unpacking, priming, and maintenance. Automated methods bring several benefits such as minimized hands-on time and excellent reproducibility.

Intelligent Packing is built into UNICORN™ software for packing AxiChrom columns with lab-scale ÄKTA™ systems (ÄKTA avant™, ÄKTA pilot™ 600) and ÄKTA process™ chromatography system. For AxiChrom 300 to 2000 columns, Intelligent Packing is also available through AxiChrom Column Controller (previously called AxiChrom Master 300–2000). AxiChrom Column Controller is a separate column control unit with touch screen user interface and motor drive for the column adapter to simplify column packing.

When packing AxiChrom 50 to 200 columns, slurry is introduced manually and adapter movement is driven by internal hydraulics. In AxiChrom 300 to 2000 columns, slurry is introduced via a resin valve in the center of the bottom bed support. The adapter is driven by an electric servomotor. Control of the resin valve and adapter is performed via AxiChrom Column Controller. The unit also offers support for other parts of the process, for example, simple step-by-step maintenance guides, which reduces risks for operator errors.

Materials of construction

Materials of construction are recognized for use in biopharmaceutical manufacture and fulfill the ASME Bioprocessing Equipment Standard. Wetted polymeric materials and elastomers meet the requirements of USP Class VI as described in USP <88> Biological Reactivity Tests *In Vivo*. The materials are free from animal-derived components or in compliance with EMA/410/01 Rev.2. Our manufacturing processes are also free from animal-derived ingredients. Pressure-retaining and wetted parts are traceable to batch level and the materials are certificated according to EN 10204 3.1 for steel parts and 2.1 or 2.2 for polymers and elastomers. For potentially corrosive processes, an available configuration of the standard platform is columns with all nonmetallic wetted flow-paths. A plastic bed support (Fig 2) can be fitted for such a purpose, or as a low-cost, single-use bed support for multipurpose facilities.

Construction materials in AxiChrom columns (Table 1) are resistant to most chemical agents used in chromatography, including buffer solutions for adsorption, elution and washing, and to solutions effective in cleaning, sanitization, and storage. Table 2 lists the chemical resistance of acrylic AxiChrom columns. For stainless-steel columns, see the operating instructions.



Fig 2. Single-use, low-cost plastic bed supports are designed for processes that risk corroding metal column parts. Quick to fit, they also add extra convenience when changing to new campaigns in multipurpose facilities.

Resin compatibility and system connectivity

AxiChrom columns are developed for use with a wide range of resin types. They can be used with traditional and high-flow resins, such as Capto and MabSelect. Combining an AxiChrom column with a high-flow resin can help drive towards lean biomanufacturing and operational excellence. Such improvements can bring more speed and better economy to downstream processing.

Depending on column size, ÄKTA avant (Fig 3), ÄKTA pilot 600, ÄKTA process, or BioProcess Modular will be the chromatography system of choice. Full utilization of the Intelligent Packing feature requires one of these systems running UNICORN software. AxiChrom 300 to 2000 columns can be integrated to a higher automation system, such as DeltaV™ distributed control system or Siemens control systems.

This integration is performed using the EtherNet/IP or PROFIBUS™ connection on AxiChrom Column Controller. The bottom valve of our BioProcess Resin Mixer, which is used for preparation of the resin slurry, is also controlled by AxiChrom Column Controller to further automate the packing and unpacking procedure.

Table 1. Materials of construction

| Component | < 300 mm i.d. | ≥ 300 mm i.d. |
|----------------------------------|---|--|
| Column tube | Glass, borosilicate 3.3 ¹ | PMMA Cast cross-linked acrylic or stainless steel ASTM S32205 |
| Seals | EPDM, FPM ³ , and UHMWPE ³ | UHMWPE (adapter), FFPM (dynamic), EPDM, FPM, FFPM, and FEP (static) ³ |
| Distributor | — | Polypropylene |
| Adapter | Stainless steel ASTM 316L ² and Polypropylene | Stainless steel ASTM 32205 ⁵ |
| Bottom plate | Stainless steel ASTM 316L ² | Stainless steel ASTM 316 ⁵ |
| Top plate/top lid | Stainless steel ASTM 316L ² | Stainless steel ASTM 316 ⁵ |
| Connection tube material | — | Stainless steel ASTM 316L or Polypropylene |
| Resin valve body | — | Polypropylene |
| Rinse nozzle body | — | Polypropylene (≥ 1200 i.d. only) |
| Tubing | PVDF ³ or Polypropylene | — |
| Stainless steel bed support ring | PEEK ³ or PTFE/PEEK | Stainless steel ASTM S32205 or polypropylene |
| Stainless steel bed support net | Stainless steel ASTM 316L ² , Polyethylene, or UHMWPE ⁶ | Stainless steel ASTM 316L, Polyethylene, or UHMWPE ⁶ |
| Plastic bed support snap-ring | PTFE | UHMWPE |
| Stand | Stainless steel ASTM 316L ⁴ and POM-C ³ | Stainless steel ASTM 316 |
| AxiChrom foot | PS ³ | — |

¹ Glass according to EU standard EN 1595

² EN 1.4404, EN 1.4432 or 1.4435 might be used. 316Ti (EN 1.4571) might be used in the AxiChrom 50 Adapter Rod. All materials are to standard EN 10028-7 and EN 10272

³ PEEK = polyether ether ketone, EPDM = ethylene propylene diene monomer rubber, FKM/FPM = fluorocarbon rubber, UHMWPE = ultra high molecular weight polyethylene, PS = polystyrene, PVDF = polyvinylidene difluoride, POM-C = polyoxymethylene, PMMA = polymethyl methacrylate, FFPM = full fluorinated polypropylene monomer

⁴ EN 1.4404 or EN 1.4436 (316) might have been used

⁵ Not wetted material

⁶ Polyethylene for 20 µm and UHMWPE for 10 µm bed supports



Fig 3. ÄKTA avant system with AxiChrom column.

Table 2. Guideline to chemical resistance for acrylic AxiChrom columns

| Chemical | Concentration ¹ | Time/cycle restrictions | Comments | Temperature limits ² | CAS no. ³ |
|---|-------------------------------|---|---|---------------------------------|----------------------|
| Acetic acid | 25% | 3 h | Cleaning-in-place (CIP) | 2°C to 30°C | 64-19-7 |
| Acetone | 2% | 1 h | Efficiency test | 2°C to 30°C | 67-64-1 |
| Ammonium sulfate | 2 M ⁴ | 5 h | Adsorption | 2°C to 30°C | 7783-20-2 |
| Benzyl alcohol | 2.0% ⁵ | 12 months (mo) | Storage | 2°C to 24°C | 100-51-6 |
| Ethanol | 20% | 12 mo and max. 0.5 bar (0.05 MPa, 72.5 psi) | Storage | 2°C to 24°C | 64-17-5 |
| Ethanol/acetic acid | 20%/10% | 3 h | CIP | 2°C to 30°C | 64-17-5/64-19-7 |
| Guanidine hydrochloride | 6 M ⁶ | 5 h | CIP | 2°C to 30°C | 50-01-1 |
| Hydrochloric acid ⁷ | 0.1 M (pH = 1) | 1 h | CIP | 2°C to 30°C | 7647-01-0 |
| Isopropanol | 30% | 1 h | CIP | 2°C to 30°C | 67-63-0 |
| Phosphoric acid | 5% | 8 h | For passivation of stainless-steel bed supports | 2°C to 30°C | 7664-38-2 |
| 1-Propanol | 20% | 16 h | Wetting plastic bed supports | 2°C to 30°C | 71-23-8 |
| Sodium chloride | 0 to 3 M ⁸ | 3 h | Purification, CIP | 2°C to 30°C | 7647-14-5 |
| Sodium hydroxide | 1 M (pH = 14) | 24 h, room temp. to 30°C | CIP | 2°C to 30°C | 1310-73-2 |
| Sodium hydroxide | 0.01 to 0.1 M (pH = 12 to 13) | 12 mo | Storage | 2°C to 30°C | 1310-73-2 |
| Sodium hydroxide/ethanol | 1 M/20% | 3 h | CIP | 2°C to 30°C | 1310-73-2/64-17-5 |
| Sodium sulfate | 1 M ⁴ | 3 h | Adsorption | 2°C to 30°C | 7757-82-6 |
| Urea | 8 M ⁴ | 5 h | Purification, CIP | 2°C to 30°C | 57-13-6 |
| Aqueous buffers commonly used in chromatography | 10 to 250 mM, pH 2 to 10 | 24 h | Equilibration, adsorption, elution | 2°C to 30°C | |

¹ When a concentration is given as a percentage, this is v/v, except in the case of benzyl alcohol, see footnote 5.

² Do not exceed the operating temperature specifications for the individual column size.

³ CAS no.: Registration number assigned by the Chemical Abstract Services (CAS), American Chemical Society.

⁴ pH in these solutions depends on the pH of the buffer, which can vary between 3 and 13.

⁵ 2.0% w/w benzyl alcohol is compatible with the polymethylmethacrylate (PMMA) material used in AxiChrom columns at room temperature for up to 1 yr.

⁶ Not for use with columns containing wetted components of stainless steel.

⁷ pH below 4.0 for stainless steel is not recommended.

⁸ For columns containing wetted stainless-steel components, max. 1.0 M NaCl is recommended.

Intelligent

AxiChrom columns help reduce operation time by, for example, enabling automated packing methods. But the intelligence of AxiChrom goes beyond automation. The purposeful design enables excellent chromatographic performance through the axial compression capabilities and the distribution system properties.

Axial compression enables more accurate and reproducible control of the packing compared to traditional packing or pack in place and is better suited to packing of modern resins. It also provides the possibility to pack more types of resins successfully.

The distribution system design is the result of combining our extensive experience within chromatography with thorough analytical methods, and computational modeling tools (computational fluid dynamics [CFD]). This gives predictable results over the entire range of scales by ensuring uniform flow through the bed, irrespective of size.

Figure 4 describes the general principles for packing of AxiChrom columns at all scales.

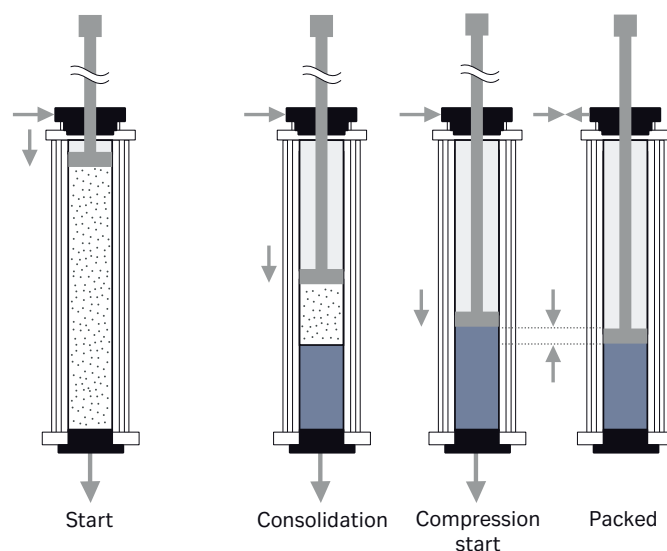


Fig 4. Intelligent Packing in AxiChrom columns. **(Start)** The adapter moves down, forcing packing liquid out of the slurry. **(Consolidation)** The slurry forms a consolidated bed. **(Compression start)** When the adapter comes into contact with the consolidated bed surface, the operator initiates bed compression in the UNICORN wizard. Compression occurs according to a predetermined packing factor. **(Packed)** The target bed height is attained.

Intelligent Packing means verified automation

Intelligent Packing enables automated packing, unpacking, and priming, as well as intuitive maintenance (Fig 5). Furthermore, the design has been extensively tested and verified experimentally for several chromatography resin families, like Capto and MabSelect (Table 3).



Fig 5. Intelligent Packing greatly simplifies the packing of AxiChrom columns used with ÄKTA systems, compared to conventional column packing.

The operational experience built into Intelligent Packing facilitates important aspects of production planning. For example, more accurate forecasting of resin consumption eliminates undue waste and reduces the amount of safety stocks needed to be held on site. In addition, the axial compression packing technique itself has a number of inherent benefits. It assists in packing optimally compressed beds, is quick to complete, and requires just one operator.

There are several beneficial features included in the Intelligent Packing function. For example, the time to complete consolidation is automatically calculated, allowing the operator to carry out other tasks. Also, once the adapter hits the consolidated bed, a graphical interface assists the operator in finishing the packing. With AxiChrom Column Controller, the option to automatically stop the packing at set packing factor or target bed height can be chosen. At this step, it is possible to prioritize exact packing factor¹ or bed height and still stay within the verified range. This function helps to increase uptime.

AxiChrom 50 to 200 columns

Packing of AxiChrom 50 to 200 columns is controlled by UNICORN software, using an ÄKTA system. The operator generates the packing method using the UNICORN Intelligent Packing wizard. Once the column is connected to the ÄKTA system, UNICORN software controls the packing. This automated procedure minimizes hands-on time and helps ensure packed beds of high quality. Intelligent Packing can also run automatic packed bed evaluation tests.

AxiChrom 50 to 200 columns are unpacked manually. The pivoting tube allows convenient emptying by tipping the tube to remove the slurry.

AxiChrom 300 to 2000 columns

AxiChrom Column Controller enables work in compliance with US FDA's 21 CFR Part 11 regulation. AxiChrom 300 to 2000 columns are controlled via AxiChrom Column Controller. The touch screen interface in AxiChrom Column Controller provides an overview of the priming, packing, unpacking, and maintenance procedures (Fig 6). Using AxiChrom Column Controller for packing large-scale AxiChrom columns allows the operator to choose between three alternative packing options. The bed may be packed until the packing procedure automatically stops at the desired packing factor or bed height. The packing procedure can also be manually ended by the operator.

Figure 7 shows the graphical interface for manually ending the packing column packing procedure.

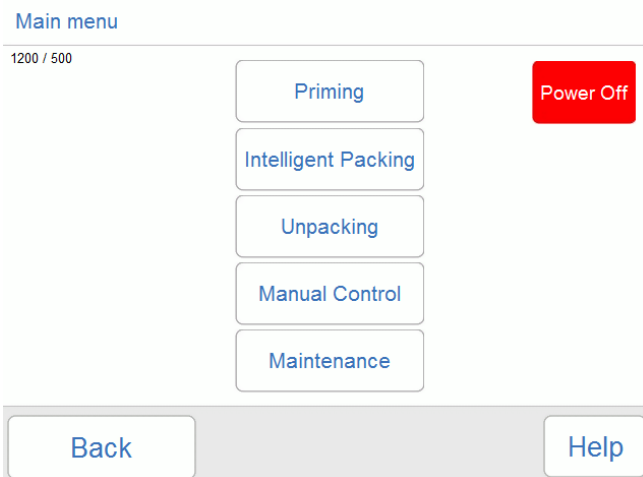


Fig 6. AxiChrom Column Controller controls the packing, unpacking, and maintenance of AxiChrom 300 to 2000 columns via a touch-screen interface.

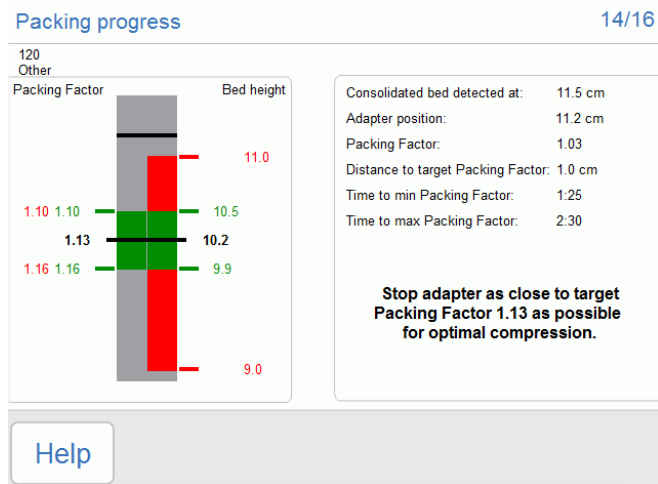


Fig 7. AxiChrom Column Controller graphical interfaces at the end of the packing procedure with manual ending of the column packing procedure. When the compression of the bed has started, the accepted packing factors and bed height are shown. The area in which the criteria for packing factor and bed height overlap is shown as green. An approved packed bed can be achieved within this green area. The adapter, highlighted in the graphics, should be stopped as close to the target packing factor as possible.

¹ Packing factor is defined as: consolidated bed height/packed bed height compared to traditional gravity-settled bed height/packed bed height.

For AxiChrom 300 to 2000 columns, UNICORN software is used as operator interface for priming, packing, and unpacking when connected to an ÄKTA process chromatography system. UNICORN Intelligent Packing wizard is used to create automated methods. Users only need to select the resin to pack, the slurry concentration of the resin, and the target bed height.

One AxiChrom Column Controller unit can be used to control between 10 and 20 (depending on model) individual columns in the range of 300 to 2000 mm i.d. during packing. Note that AxiChrom Column Controller is not needed during chromatography operation.

AxiChrom 300 to 2000 columns are equipped with a two-position resin valve at the center of the bottom bed support. These two positions enable filling, packing, and unpacking without adjusting the assembled column.

The adapter position is monitored with millimeter accuracy thanks to the electric servomotor on large-scale columns (300–2000).

AxiChrom 300 to 2000 columns unpack easily at high slurry concentrations. This allows for minimal volumes to handle and thereby decreases the need for costly storage. Verified unpacking methods for preprogrammed resins are available via the UNICORN wizard or AxiChrom Column Controller.

Standardized bypass valves

Standardized bypass valves are available to facilitate CIP and transport of columns. Four sizes are available depending on the column size, see *Ordering information*. Each size of bypass valve kit is suitable for use with both 300 mm and 500 mm column tube heights.

Intuitive

AxiChrom columns are easy to operate. Even the largest sizes can be handled safely by a single operator. The step-by-step interface guides users through key priming, packing, unpacking, and maintenance steps. Previous experience or extensive training is not necessary, which makes it easy to quickly move columns between projects and/or locations. As well as helping avoid operator-error, these intuitive aids also allow for maximized uptime and column use.

AxiChrom 50 to 200 columns feature a simple pivot design that eliminates lifting and promotes safer operation. Emptying is simple and accomplished without unnecessary waste of resin. Access to bed supports and O-rings is straightforward and most maintenance can be performed without disassembling the whole column.

The swing-out, hoist-free design of AxiChrom 300 to 2000 columns (Fig 8) has many practical advantages. As there is no need to move it from the production site for maintenance, it requires less space than a conventional column. Also, as no hoists are needed, it provides a safer working environment.

Furthermore, access to all relevant parts is easy. The beneficial design together with clear and concise interactive instructions from AxiChrom Column Controller increases uptime. For example, disassembly, changing all wetted parts, and reassembly takes about one hour for AxiChrom 600.



Fig 8. AxiChrom column in swing-out mode provides easy access to bed supports and O-rings. In multipurpose facilities, changing plastic bed supports for a new campaign is quick and hassle free.

AxiChrom columns are delivered with a comprehensive documentation package. This consists of spare parts as well as accessories lists, materials certificates, assembly drawings, operating instructions, and more. The number of spare parts needed to be kept in stock is low compared to other column series.

Predictable

To secure scalable and predictable performance, an analytical method for computing the mathematical residence-time distribution of the liquid distribution system was applied during column design. CFD methods were then used to validate the analytical results. They were also used for detailed studies analyzing more complicated geometries.

The chosen design was verified experimentally by height equivalent of a theoretical plate (HETP) and asymmetry testing from small to large column diameters (Table 3). Plate number and asymmetry results confirmed the success of the column design.

The range of modeled mobile phase distribution systems ensures uniform flow through the bed, independent of size, thereby promoting reproducible results over the entire column range. Irrespective of experience, users can thus expect the same good separation efficiency when scaling up or down. Together with Intelligent Packing, this promotes smooth and predictable technology transfer between departments and sites or to contract manufacturing organizations (Fig 9). Model protein elution and HETP tests confirm this consistent chromatographic performance (Fig 10, 11, and 12).

Table 3. Verification of AxiChrom 50 to 1600 columns with three commonly used BioProcess resin platforms (Capto, MabSelect, and Sepharose)

| Resin | Column diameter (mm) | Bed height (cm) | N/m ^{1,2} | h ^{1,3} | A _s ^{1,4} |
|-------------------|----------------------|-----------------|--------------------|------------------|-------------------------------|
| MabSelect Prisma™ | 50 | 20 | 11 000 | 1.5 | 1.0 |
| | 50 | 40 | 11 400 | 1.5 | 0.9 |
| | 100 | 10 | 12 000 | 1.4 | 1.1 |
| | 100 | 40 | 10 900 | 1.5 | 1.1 |
| | 140 | 20 | 12 300 | 1.4 | 1.1 |
| | 200 | 10 | 11 200 | 1.5 | 1.3 |
| | 200 | 20 | 11 700 | 1.4 | 1.1 |
| | 300 | 20 | 11 000 | 1.6 | 1.2 |
| | 300 | 30 | 10 800 | 1.5 | 1.2 |
| | 600 | 20 | 10 300 | 1.5 | 1.1 |
| | 600 | 30 | 10 100 | 1.6 | 1.1 |
| | 1000 | 10 | 11 700 | 1.5 | 1.3 |
| | 1000 | 20 | 11 100 | 1.6 | 1.2 |
| | 1600 | 10 | 10 900 | 1.6 | 1.3 |
| | 1600 | 30 | 10 000 | 1.7 | 1.2 |
| Capto Q | 50 | 20 | 6900 | 1.6 | 1.2 |
| | 50 | 40 | 7100 | 1.6 | 1.0 |
| | 70 | 20 | 6600 | 1.7 | 1.2 |
| | 70 | 30 | 6200 | 1.8 | 1.3 |
| | 100 | 20 | 7200 | 1.5 | 1.0 |
| | 100 | 40 | 7300 | 1.5 | 1.1 |
| | 140 | 20 | 6400 | 1.7 | 1.2 |
| | 140 | 40 | 6700 | 1.7 | 1.0 |
| | 200 | 20 | 7800 | 1.4 | 1.0 |
| | 200 | 40 | 7600 | 1.5 | 1.0 |
| | 400 | 20 | 7500 | 1.6 | 1.2 |
| | 400 | 40 | 7200 | 1.6 | 1.1 |
| | 1000 | 10 | 7500 | 1.6 | 1.3 |
| Capto S | 50 | 20 | 6500 | 1.6 | 1.0 |
| | 100 | 20 | 6900 | 1.4 | 0.9 |
| | 100 | 40 | 7100 | 1.4 | 1.0 |
| | 200 | 40 | 7300 | 1.4 | 0.9 |
| | 400 | 10 | 5300 | 2.1 | 1.3 |
| | 1000 | 15 | 7000 | 1.5 | 1.2 |
| | 1600 | 20 | 4700 | 2.4 | 1.3 |
| Capto DEAE | 600 | 20 | 7200 | 1.6 | 1.2 |
| Capto adhere | 100 | 20 | 8200 | 1.5 | 1.1 |
| | 100 | 40 | 8000 | 1.5 | 1.0 |
| | 200 | 20 | 8600 | 1.4 | 1.1 |
| | 600 | 20 | 8700 | 1.5 | 1.3 |
| | 600 | 20 | 8900 | 1.5 | 1.2 |
| | 600 | 35 | 7700 | 1.5 | 1.1 |
| Capto MMC | 400 | 40 | 8300 | 1.2 | 1.2 |
| | 600 | 35 | 9500 | 1.4 | 1.1 |
| | 600 | 20 | 8800 | 1.5 | 1.3 |
| | 1000 | 20 | 7800 | 1.7 | 1.3 |
| Capto Q ImpRes | 50 | 40 | 15 400 | 1.5 | 1.0 |
| | 300 | 20 | 15 100 | 1.6 | 1.1 |
| Capto SP ImpRes | 50 | 20 | 15 800 | 1.4 | 1.0 |
| | 300 | 20 | 16 300 | 1.5 | 1.2 |
| | 300 | 40 | 14 000 | 1.6 | 1.1 |
| | 600 | 10 | 15 700 | 1.5 | 1.3 |
| | 600 | 30 | 15 900 | 1.4 | 1.1 |
| | 1600 | 15 | 13 200 | 1.9 | 1.1 |

Table 3 continued

| Resin | Column diameter (mm) | Bed height (cm) | N/m ^{1,2} | h ^{1,3} | A _s ^{1,4} |
|---------------------------------------|-------------------------|--------------------|--------------------|------------------|-------------------------------|
| Capto adhere ImpRes | 50 | 40 | 13 700 | 1.7 | 1.0 |
| | 300 | 20 | 14 200 | 1.6 | 1.3 |
| Capto MMC ImpRes | 50 | 40 | 14 000 | 1.7 | 0.9 |
| | 100 | 10 | 15 700 | 1.5 | 1.1 |
| | 300 | 20 | 16 000 | 1.5 | 1.2 |
| MabSelect | 50 | 20 | 7900 | 1.5 | 1.1 |
| | 100 | 20 | 8200 | 1.4 | 1.0 |
| | 140 | 20 | 7900 | 1.5 | 1.2 |
| MabSelect Xtra™ | 400 | 20 | 7400 | 1.7 | 1.2 |
| | 600 | 20 | 8100 | 1.7 | 1.2 |
| MabSelect SuRe™ | 300 | 20 | 8100 | 1.4 | 1.1 |
| | 300 | 40 | 8000 | 1.5 | 1.1 |
| | 400 | 20 | 8300 | 1.4 | 1.1 |
| | 400 | 35 | 8200 | 1.4 | 1.1 |
| | 600 | 20 | 8200 | 1.4 | 1.2 |
| | 1000 | 20 | 7300 | 1.5 | 1.1 |
| | 1600 | 20 | 6100 | 1.8 | 1.2 |
| MabSelect SuRe LX | 50 | 20 | 6600 | 1.7 | 1.0 |
| | 100 | 20 | 8500 | 1.3 | 1.0 |
| | 300 | 20 | 7800 | 1.4 | 1.1 |
| DEAE Sepharose Fast Flow | 1600 | 10 | 4700 | 2.3 | 1.2 |
| | 1600 | 20 | 5500 | 1.9 | 1.2 |
| | 1600 | 30 | 5200 | 2.0 | 1.1 |
| SP Sepharose Fast Flow | 50 | 10 | 6600 | 1.7 | 1.3 |
| | 70 | 10 | 7100 | 1.6 | 1.3 |
| | 70 | 30 | 7200 | 1.5 | 1.0 |
| | 100 | 10 | 7600 | 1.4 | 1.1 |
| | 100 | 30 | 7700 | 1.4 | 1.0 |
| | 140 | 10 | 6100 | 1.8 | ND |
| | 140 | 30 | 6400 | 1.6 | 1.1 |
| | 200 | 10 | 7000 | 1.5 | 1.2 |
| | 200 | 30 | 7000 | 1.5 | 1.1 |
| | 400 | 10 | 5500 | 2.0 | 1.4 |
| | 400 | 30 | 7100 | 1.6 | 1.2 |
| | 1000 | 30 | 6000 | 1.9 | 1.2 |
| | 1000 | 10 | 5500 | 2.0 | 1.3 |
| SP Sepharose High Performance | 400 | 10 | 15 900 | 1.9 | 1.4 |
| | 600 | 10 | 12 000 | 2.4 | 1.3 |
| | 1000 | 10 | 16 800 | 1.8 | 1.4 |
| Sepharose Big Beads | 1000 | 10 | 2700 | 1.9 | 1.3 |
| | 1000 | 30 | 3500 | 1.5 | 1.1 |
| Phenyl Sepharose Fast Flow (high sub) | 600 | 20 | 6700 | 1.7 | 1.3 |

¹ N/m, h, and A_s results are average values from three to five packings.² N/m = plate number per meter³ h = reduced plate height = HETP/particle diameter⁴ A_s = asymmetry factor

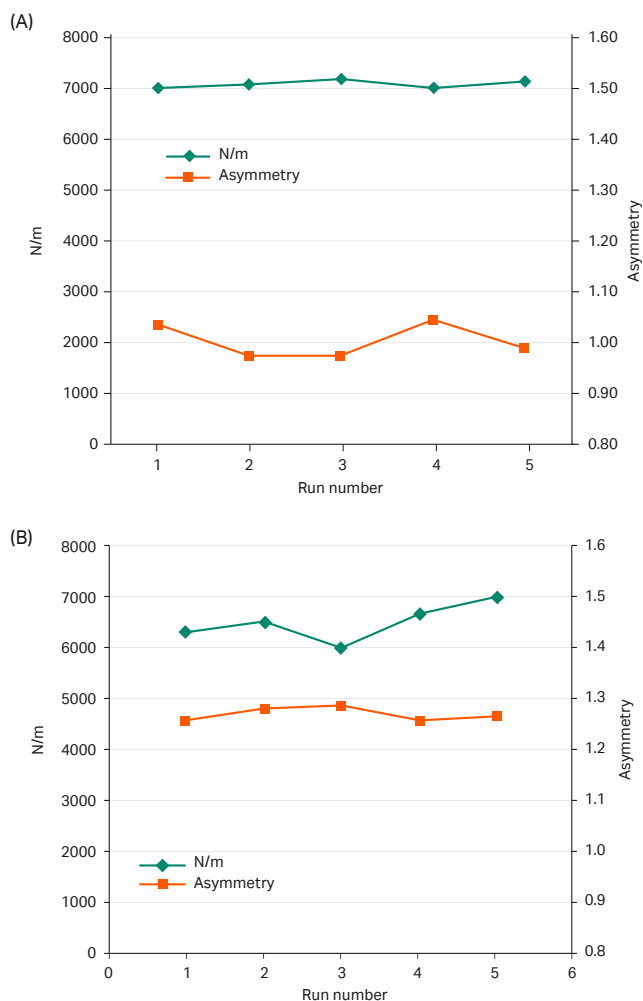


Fig 9. AxiChrom shows excellent reproducibility independent of operator or column size. (A) HETP test on Capto Q packed in AxiChrom 50 at 40 cm bed height; (B) HETP tests on MabSelect SuRe packed in AxiChrom 1600 at 20 cm bed height. Packings for (A) and (B) were performed by five and three different operators, respectively. The degree of variation in plates per meter and asymmetries is similar in AxiChrom 50 and 1600 columns, even though columns were packed with different resins. N/m = plate number per meter.

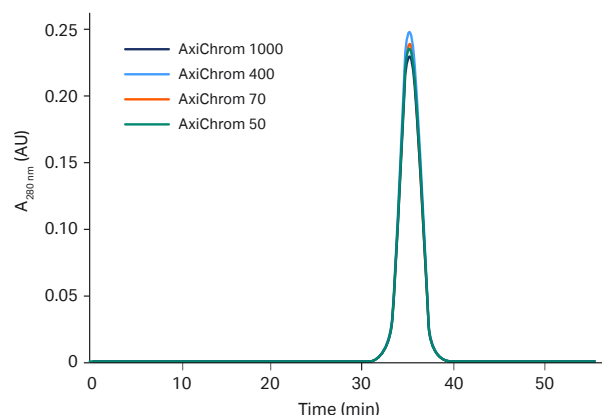


Fig 10. HETP tests on SP Sepharose Fast Flow packed to 20 cm bed height in different AxiChrom 50, 70, 400, and 1000 columns.

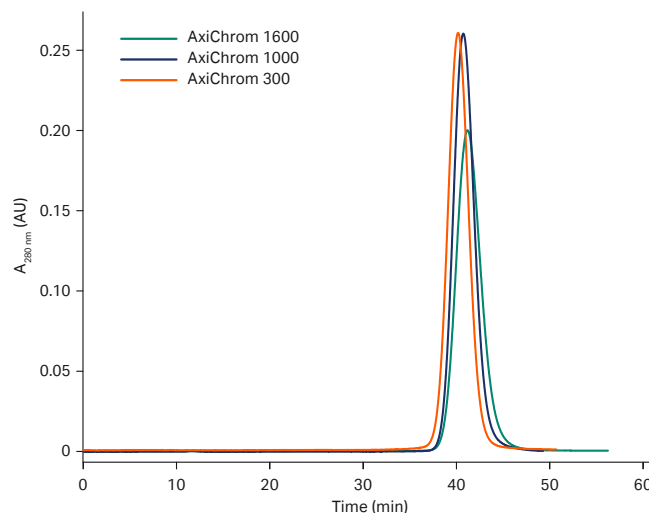


Fig 11. HETP tests on MabSelect SuRe packed to 20 cm bed height in different AxiChrom 300, 1000, and 1600 columns.

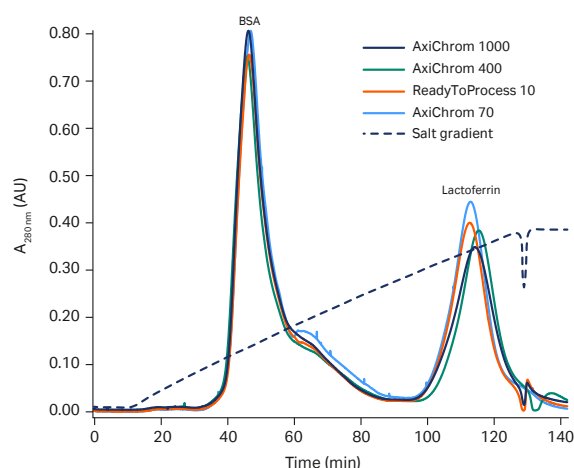


Fig 12. Separation of BSA and lactoferrin on SP Sepharose Fast Flow in different AxiChrom and ReadyToProcess™ columns.

Documentation

Comprehensive documentation (including IQ/OQ documents) simplifies validation, thereby reducing start-up time. The columns are delivered with an extensive documentation package including general specification, bill of materials, assembly drawing, spare parts list, and site preparation guide. The same level of documentation is available for all column sizes.

High standards of sanitary design

One key aspect of cGMP production is operation at hygienic standards. AxiChrom columns have been demonstrated to meet high standards of sanitary design, both for columns with stainless steel as well as plastic bed supports. For example, the efficiency of microbial sanitization and endotoxin clearance has been investigated by challenge testing. Columns, packed with Sepharose Fast Flow resin, were challenged with *E. coli*

and endotoxins. They were incubated for 16 to 20 h at room temperature before being treated with 1 M sodium hydroxide (NaOH) and then sampled.

The results of both studies fulfilled the set acceptance criteria proving sanitization with 1 M NaOH to be effective. Despite high levels of microbial contamination, no challenging organisms were found after treatment. In addition, 1 M NaOH gave a 6-log reduction of endotoxin concentration. The final level in the column flowthrough was less than 0.05 EU/mL, which is below the USP recommendation for water for injection.

Full study details are described in application note *Sanitization and endotoxin clearance in AxiChrom columns*, CY13214.

Accessories and configurations

Accessories for AxiChrom 50 to 200

A list of standard accessories for AxiChrom 50 to 200 columns are found in *Ordering information*.

Accessories for AxiChrom 300 to 1600

There are a number of accessories available for AxiChrom 300 to 1600 columns. These include tubings, T-junctions, reducers, gaskets and clamps, manual valves, and Media stirrer.

AxiChrom Column Controller is an essential accessory for AxiChrom 300 to 1600 columns. To simplify maintenance, it is also recommended to include a tool kit in the first order.

To get the most out of your column, a wheel kit is highly recommended. The wheel kit is used to facilitate installation as well as to move the column short distances. It is used together with a moving device, for example, the PowerAttack or MASTERMOVER™, using an adapter specific for AxiChrom columns. The wheel kit also includes a jack useful for leveling the column.

Accessories highly recommended for AxiChrom 300 to 1600:

The bypass valve kit facilitates connections to process systems. The burst discs are recommended as a safety precaution when the column is in operation. A lifting device is also recommended for safer and faster maintenance work on AxiChrom 1200 to 1600 columns. The lifting device is, for example, used for removal of bed supports. It is essential for certain maintenance operations.

Dynamic wizards for accessories and spare parts are available through the sales configurator. The wizards will recommend a number of accessories and spare parts exactly matching the column and interface to a chromatography system. This facilitates easy, fast, and correct selection, fulfilling the same standards as the column.

Configurable AxiChrom columns

Smaller columns without standard code numbers and all larger columns with diameters of 300 to 1600 mm are configurable and ordered via a sales configurator (Table 4). Columns can be tailored to requirements using this configurator. The configurator also creates an extensive documentation package including general specification, bill of materials, assembly drawing, spare parts list, site preparation guide, as well as a price quotation.

Table 4. AxiChrom configuration options

| Component | Option |
|--|------------------------------------|
| Bed support porosity | 10 or 20 µm |
| Bed support material | Stainless steel or PE ¹ |
| Column tube material (AxiChrom 300–1600) | Stainless steel or acrylic |
| Tube connections (AxiChrom 300–1600) | Stainless steel or PE ¹ |

¹ PE = polyethylene

Please contact a your sales representative for assistance in configuring your column and system.

Preventive maintenance (PM) for enhanced performance

PM keeps your BioProcess equipment running in peak condition and forms the core of our service offering. Prevention is always better than cure. Regular PM visits are more cost effective and predictable than unplanned repairs. PM is an integral part of our equipment design process, and our maintenance services are optimized through the collective global experience of maintaining thousands of BioProcess systems.

Preventive maintenance

- helps ensure the quality of your results
- extends the life of your BioProcess equipment
- enables traceability via visit records

Service agreements

Our service agreement, scheduled on customer needs, saves time, maximizes productivity, and allows you to concentrate on your results. Regular PM visits are performed throughout the agreement period. Priority response from our trained service engineers, as well as timely access to secured, product-specific wear parts, will help maximize equipment uptime and the quality of your results. Service agreement rates are guaranteed for the duration of the agreement, giving you a predictable ownership cost. Figure 13 lists service offerings available for AxiChrom columns.

PM for columns

A column PM includes:

- all column O-rings
- resin valve/nozzle O-rings

Plastic bed supports are included, while stainless steel bed supports are optional and can be included based on your requirements.

Our general recommendation for normal usage of our BioProcess columns is one PM visit once every two years. For frequent usage we recommend one PM visit yearly. Our service team can advise on a frequency that suits your needs.

Documentation

PM protocols have been developed to meet the requirements of each type of BioProcess equipment. Our service engineers ensure that all changes are carefully evaluated, verified, documented, and reviewed.













| | | PMs | Parts | Travel and labor | Accelerated response option |
|---|--|---|---|---|---|
| EssentialCare  | One annual PM visit. |  | | | |
| FullCare  | A 12-mo, full-coverage service agreement that includes one annual PM visit, all parts, and travel and labor costs. |  |  |  |  |
| ExtendedCare  | A 24-mo, full-coverage service agreement that includes one PM visit, all parts, and travel and labor costs. |  |  |  |  |

Fig 13. Service offerings for AxiChrom columns.

Column platform specifications and column volume guide

The main column platform specifications are given in Table 5. A guide to column volumes is found in Table 6.

Table 5. AxiChrom column platform specifications

| AxiChrom columns | 50 | | 70 | | 100 | | 140 | | 200 | |
|--|----------------------------|--------|------------------------------|--------|-----------------------------|---------|-----------------------------|-----------|----------------------------|---------|
| Inner column diameter (mm) | 50 | | 70 | | 100 | | 140 | | 200 | |
| Column type | 50/300 | 50/500 | 70/300 | 70/500 | 100/300 | 100/500 | 140/300 | 140/500 | 200/300 | 200/500 |
| Bed height (cm) using Intelligent Packing ¹ | 10–30 | 30–50 | 10–30 | 30–50 | 10–30 | 30–50 | 10–30 | 30–50 | 10–30 | 30–50 |
| Weight, empty column ² (kg) | 6.5 | 7.5 | 10 | 11.5 | 16.3 | 19.3 | 28.5 | 31.5 | 41.5 | 45.5 |
| Weight, column stand (kg) | 7 | 7.5 | 7 | 7.5 | 7 | 7.5 | 23.5 | 25.0 | 23.5 | 25.0 |
| Max. operating work height (mm) | 1400 | 1700 | 1650 | 1800 | 1650 | 1800 | 2000 | 2100 | 2000 | 2100 |
| Max. operating pressure | 10 bar (145 psi, 1 MPa) | | 8 bar (116 psi, 0.8 MPa) | | 8 bar (116 psi, 0.8 MPa) | | 6 bar (87 psi, 0.6 MPa) | | 5 bar (73 psi, 0.5 MPa) | |
| Max. packing pressure | 20 bar (290 psi, 2 MPa) | | 15 bar (218 psi, 1.5 MPa) | | 10 bar (145 psi, 1 MPa) | | 8 bar (116 psi, 0.8 MPa) | | 6 bar (87 psi, 0.6 MPa) | |
| Footprint, foot (mm × mm) | 352 × 352 | | 350 × 360 | | | | | 615 × 550 | | |
| Footprint, stand (mm × mm) | | | | | | | | | | |
| Operating temperature (°C) | | | | | | | | | | |
| Adapter movement | 2–30 Internal hydraulic | | | | | | | | | |
| Bed support (µm) | 10, 20 ³ | | | | | | | | | |

Table 5 continued

| AxiChrom columns | 300 | | 400 | | 450 | | 600 | | 800 | | 1000 | |
|--|-------------------------|---------|------------|---------|------------|---------|------------|---------|-------------|---------|-------------|----------|
| Inner column diameter (mm) | 300 | | 400 | | 450 | | 600 | | 800 | | 1000 | |
| Column type | 300/300 | 300/500 | 400/300 | 400/500 | 450/300 | 450/500 | 600/300 | 600/500 | 800/300 | 800/500 | 1000/300 | 1000/500 |
| Recommended bed height ¹ (cm) | 10–30 | 10–50 | 10–30 | 10–50 | 10–30 | 10–50 | 10–30 | 10–50 | 10–30 | 10–50 | 10–30 | 10–50 |
| Weight, empty column ⁴ (kg) | 420 | 440 | 460 | 490 | 710 | 760 | 840 | 910 | 2175 | 2265 | 2600 | 2720 |
| Min. height (mm) | 1450 | 1710 | 1460 | 1720 | 1480 | 1740 | 1590 | 1850 | 1880 | 2040 | 1890 | 2150 |
| Max. operating work height (mm) | 2050 | 2570 | 2060 | 2580 | 2080 | 2600 | 2190 | 2710 | 2480 | 3000 | 2490 | 3010 |
| Max. height for maintenance (mm) | 2200 | 2720 | 2200 | 2720 | 2230 | 2750 | 2340 | 2860 | 2630 | 3150 | 2650 | 3170 |
| Max. operating pressure | 4 bar (58 psi, 0.4 MPa) | | | | | | | | | | | |
| Footprint, foot (mm × mm) | 520 × 1110 | | 600 × 1110 | | 620 × 1110 | | 780 × 1180 | | 1080 × 1470 | | 1300 × 1720 | |
| Operating temperature (°C) | 2–30 | | | | | | | | | | | |
| Adapter movement | Servomotor | | | | | | | | | | | |
| Bed support (µm) | 10, 20 | | | | | | | | | | | |

| AxiChrom columns | 1200 | | 1400 | | 1600 | |
|--|-------------------------|----------|-------------|----------|-------------|----------|
| Inner column diameter (mm) | 1200 | | 1400 | | 1600 | |
| Column type | 1200/300 | 1200/500 | 1400/300 | 1400/500 | 1600/300 | 1600/500 |
| Recommended bed height ¹ (cm) | 10–30 | 10–50 | 10–30 | 10–50 | 10–30 | 10–50 |
| Weight, empty column ⁴ (kg) | 4945 | 5135 | 7370 | 7610 | 9680 | 9960 |
| Min. height (mm) | 2200 | 2480 | 2380 | 2640 | 2390 | 2650 |
| Max. operating work height (mm) | 2840 | 3360 | 3000 | 3520 | 3010 | 3530 |
| Max. height for maintenance (mm) | 3000 | 3520 | 3160 | 3680 | 3170 | 3690 |
| Max. operating pressure | 4 bar (58 psi, 0.4 MPa) | | | | | |
| Footprint, foot (mm × mm) | 1510 × 2020 | | 1740 × 2220 | | 1960 × 2320 | |
| Operating temperature (°C) | 15–30 | | | | | |
| Adapter movement | Servomotor | | | | | |
| Bed support (µm) | 10, 20 | | | | | |

¹ Adapter stroke length: AxiChrom 50–200 AxiChrom 300–1000 AxiChrom 1200–1600

Short column tube: min/max limits 0–35 cm 1–57 cm 1–55 cm

Long column tube: min/max limits 30–60 cm 1–83 cm 1–81 cm

² Weight includes stainless steel bed support

³ 20 µm supports are standard; 10 µm can be ordered separately

⁴ Weights are for PMMA column tube and stainless steel bed support

Table 6. Guide to column volumes for different AxiChrom column inner diameters and bed heights

| AxiChrom columns | 50 | | | 70 | | | 100 | | | 140 | | | 200 | | |
|--------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|
| Bed height ¹ (cm) | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 |
| Column volume ² (L) | 0.2 | 0.6 | 1.0 | 0.4 | 1.2 | 1.9 | 0.8 | 2.4 | 3.9 | 1.5 | 4.6 | 7.7 | 3.1 | 9.4 | 15.7 |

| AxiChrom columns | 300 | | | 400 | | | 450 | | | 600 | | | 800 | | | 1000 | | |
|--------------------------------|-----|----|----|-----|----|----|-----|----|----|-----|----|-----|-----|-----|-----|------|-----|-----|
| Bed height ¹ (cm) | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 |
| Column volume ² (L) | 7 | 21 | 35 | 13 | 38 | 63 | 16 | 48 | 80 | 28 | 85 | 141 | 50 | 151 | 251 | 79 | 236 | 393 |

| AxiChrom columns | 1200 | | | 1400 | | | 1600 | | |
|--------------------------------|------|-----|-----|------|-----|-----|------|-----|------|
| Bed height ¹ (cm) | 10 | 30 | 50 | 10 | 30 | 50 | 10 | 30 | 50 |
| Column volume ² (L) | 113 | 339 | 565 | 154 | 462 | 770 | 201 | 603 | 1005 |

¹ Listed bed heights are examples. Other bed heights within the adapter stroke length are also possible.

² Column volumes do not take medium compression into consideration.

Ordering information

| Columns* | Product code |
|--|--------------|
| AxiChrom 50/300/Glass/10PE [†] | 29656653 |
| AxiChrom 50/300/Glass/20PE | 29016534 |
| AxiChrom 50/300/Glass/10SS [†] | 29656654 |
| AxiChrom 50/300/Glass/20SS | 28901831 |
| AxiChrom 50/500/Glass/10PE [†] | 29656655 |
| AxiChrom 50/500/Glass/20PE | 29656407 |
| AxiChrom 50/500/Glass/10SS [†] | 29656656 |
| AxiChrom 50/500/Glass/20SS | 28901841 |
| AxiChrom 70/300/Glass/10PE [†] | 29656657 |
| AxiChrom 70/300/Glass/20PE | 29016537 |
| AxiChrom 70/300/Glass/10SS [†] | 29656658 |
| AxiChrom 70/300/Glass/20SS | 28901840 |
| AxiChrom 70/500/Glass/10PE [†] | 29656659 |
| AxiChrom 70/500/Glass/20PE | 29656413 |
| AxiChrom 70/500/Glass/10SS [†] | 29656661 |
| AxiChrom 70/500/Glass/20SS | 28901847 |
| AxiChrom 100/300/Glass/10PE [†] | 29656662 |
| AxiChrom 100/300/Glass/20PE | 29016536 |
| AxiChrom 100/300/Glass/10SS [†] | 29656663 |
| AxiChrom 100/300/Glass/20SS | 28903274 |
| AxiChrom 100/500/Glass/10PE [†] | 29656667 |
| AxiChrom 100/500/Glass/20PE | 29656414 |
| AxiChrom 100/500/Glass/10SS [†] | 29656668 |
| AxiChrom 100/500/Glass/20SS | 28903276 |
| AxiChrom 140/300/Glass/10PE [†] | 29656669 |
| AxiChrom 140/300/Glass/20PE | 29016535 |
| AxiChrom 140/300/Glass/10SS [†] | 29656670 |
| AxiChrom 140/300/Glass/20SS | 28907702 |
| AxiChrom 140/500/Glass/10PE [†] | 29656671 |
| AxiChrom 140/500/Glass/20PE | 29656415 |
| AxiChrom 140/500/Glass/10SS [†] | 29656672 |
| AxiChrom 140/500/Glass/20SS | 28943927 |
| AxiChrom 200/300/Glass/10PE [†] | 29656673 |
| AxiChrom 200/300/Glass/20PE | 29016533 |
| AxiChrom 200/300/Glass/10SS [†] | 29656674 |
| AxiChrom 200/300/Glass/20SS | 28907703 |
| AxiChrom 200/500/Glass/10PE [†] | 29656675 |
| AxiChrom 200/500/Glass/20PE | 29656416 |
| AxiChrom 200/500/Glass/10SS [†] | 29656676 |
| AxiChrom 200/500/Glass/20SS | 28943928 |

*AxiChrom 50–1000 columns are available with 10 µm and 20 µm stainless steel bed supports as well as 10 µm and 20 µm plastic bed supports. Available tube lengths are 300 mm and 500 mm. Please see additional information in Table 4 and 5. Configurations not listed above are ordered via the Cytiva sales representative.

[†]Includes a column with a 20 µm bed support, and parts to exchange to a 10 µm bed support.

cytiva.com/axichrom

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CY10003-03May24-DF

| Parts/accessories | Quantity | Product code |
|--|----------|--------------|
| AxiChrom Column Controller | 1 | 29717831 |
| Pivot stand 50/70/100–300 | 1 | 28401709 |
| Pivot stand 50/70/100–500 | 1 | 28401710 |
| Adapter holder 140 | 1 | 28948118 |
| Adapter holder 200 | 1 | 28948119 |
| Mechanical locking 50 | 1 | 28401839 |
| Mechanical locking 70 | 1 | 28401840 |
| Mechanical locking 100 | 1 | 28401841 |
| Mechanical locking 140 | 1 | 28943388 |
| Mechanical locking 200 | 1 | 28943353 |
| Tool kit complete AxiChrom 50–200 | 1 | 28944261 |
| Tool kit small AxiChrom 50–200 | 1 | 28936136 |
| Torque driver kit AxiChrom | 1 | 28936139 |
| Torque wrench kit AxiChrom | 1 | 28936137 |
| Tubing Kit for connecting AxiChrom 50 on bench to ÄKTApilot, i.d. 1.7 mm | 1 | 28905676 |
| Tubing Kit for connecting AxiChrom 50–70 on floor to ÄKTApilot, i.d. 1.7 mm | 1 | 28913613 |
| Tubing kit for connecting AxiChrom 70–100 on floor to ÄKTApilot, i.d. 2.9 mm | 1 | 28913614 |
| Tubing kit for connecting AxiChrom 50–70 ÄKTA avant, desk, i.d. 1.7 mm | 1 | 28988889 |
| Tubing kit for AxiChrom 50–70 on floor to ÄKTA avant, i.d. 1.7 mm | 1 | 28988892 |
| Silicone tubing kit AxiChrom 140, i.d. 3.2 mm (ÄKTApilot) | 1 | 29701674 |
| Silicone tubing kit AxiChrom 140, i.d. 4.8 mm (ÄKTApilot) | 1 | 29701672 |
| Silicone tubing kit AxiChrom 200, i.d. 6.4 mm (ÄKTApilot) | | 29701671 |
| Silicone tubing kit AxiChrom 140, i.d. 3.2 (ÄKTApilot) | 1 | 29701677 |
| Silicone tubing kit AxiChrom 140, i.d. 4.8 (ÄKTApilot) | 1 | 29701676 |
| Silicone tubing kit AxiChrom 200, i.d. 6.4 (ÄKTApilot) | 1 | 29701675 |
| Media stirrer 1 (80 mm, for AxiChrom 100/140) | 1 | 28919103 |
| Media stirrer 1 (40 mm, for AxiChrom 50/70) | 1 | 28923180 |
| Media stirrer 1 (150 mm, for AxiChrom 200) | 1 | 28919104 |
| Bypass valve kit, ½ inch for AxiChrom 300 | 1 | 29359104 |
| Bypass valve kit, ¾ inch for AxiChrom 400–600 | 1 | 29359106 |
| Bypass valve kit, 1 inch for AxiChrom 800–1000 | 1 | 29359197 |
| Bypass valve kit, 1½ inch for AxiChrom 1200–1600 | 1 | 29359199 |
| Wheel kit AxiChrom 300 | 1 | 28938192 |
| Wheel kit AxiChrom 400 | 1 | 28938193 |
| Wheel kit AxiChrom 450 | 1 | 28955429 |
| Wheel kit AxiChrom 600 | 1 | 28938194 |
| Wheel kit AxiChrom 800 | 1 | 28938196 |
| Wheel kit AxiChrom 1000 | 1 | 28938197 |
| Wheel kit AxiChrom 1200–1600 | 1 | 29090400 |
| Moving arm 1200/1400 (wheel kit) | 1 | 29091373 |
| Moving arm 1600 (wheel kit) | 1 | 29091014 |

Please see *Accessories and configurations* for information on accessories for AxiChrom 300 to 1600 columns.

